UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,104	05/16/2001	Sanford H. Barsky	30435.73USWO	3615

22462 7590 05/28/2002

GATES & COOPER LLP
HOWARD HUGHES CENTER
6701 CENTER DRIVE WEST, SUITE 1050
LOS ANGELES, CA 90045

EXAMINER	
CROUCH, DEBORAH	
ART UNIT	PAPER NUMBER
1632	4

DATE MAILED: 05/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/856,104	Applicant(s) BARSKY ET AL.	
	Examiner Deborah Crouch	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-49 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicant is requested to review claims 20,21,24,25,34,35,36,37,38,39,40,,44,45 and 46. They each are product claims depending from a method claim. As this would constitute improper claim dependency in an examination, applicant may wish to amend these claims in response to this office action. However, any amendment to these claims, or other similar claims, may result in a subsequent restriction/election requirement being issued. This request is being offered as a courtesy to applicant and is not to be considered a rejection or a requirement of the following restriction/election requirement.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-27, drawn to a human inflammatory breast cancer xenograft, an in vitro culture of a human inflammatory breast cancer xenograft, method of generating a human breast cancer xenograft, a nonhuman animal model for inflammatory breast cancer, a method to evaluate an agent for treating inflammatory breast cancer and a method to evaluate an agent for identifying inflammatory breast cancer, classified in class 800, subclasses 3 and 10 as examples.

II. Claims 28 and 29, drawn to a method of identifying a molecule whose expression is modulated in inflammatory breast cancer disease, classified in class 435, subclass 29.

III. Claims 30 and 43-47, drawn to a method of inhibiting the growth of an inflammatory breast cancer disease comprising administering an anti-E cadherin antibody, classified in class 424, subclass 130.1.

IV. Claim 31, 34 and 35, drawn to a method of detecting an inflammatory breast cancer metastases in vivo comprising administering an anti-E cadherin antibody , classified in class 424, subclass 130.1.

V. Claim 32 and 33, drawn to a conjugate comprising an anti-E cadherin antibody joined to a cytotoxic agent, classified in class 530, subclass 387.1.

VI. Claim 36-40, drawn to a Fv molecule comprising the antigen binding site of an anti-E cadherin antibody and an Fab molecule or an Fab' molecule comprising the antigen binding site of an anti-E cadherin antibody, classified in class 530, subclass 387.1.

VII. Claims 41, drawn to a bispecific antibody where one antigen binding site comprises the antigen binding site of an anti-E cadherin antibody, classified in class 530, subclass 387.1.

VIII. Claim 42, drawn to antibody comprising human and murine antigen binding region, where the antibody inhibits the binding of antibody HECD-1 to E-cadherin, classified in class 530, subclass 387.1.

IX. Claims 48 and 49, drawn to a kit comprising an isolated E-cadherin specific polypeptide comprising an antigen binding site from an antibody capable of binding to E-cadherin, instructions and a container and an article of manufacture comprising a container, a label and a reagent comprising an antigen binding site from an antibody capable of binding to E-cadherin, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the human inflammatory breast cancer xenograft can be used in a method of detecting an inflammatory breast cancer metastases.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the human

inflammatory breast cancer xenograft can be used in a method of detecting an inflammatory breast cancer metastases.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the human inflammatory breast cancer xenograft can be used in a method of identifying a molecule whose expression is modulated in inflammatory breast cancer.

Invention I and any of inventions V-IX are mutually exclusive and independent. The xenograft of invention I does not require any of the antibodies, kits or articles of manufacture of inventions V-IX, and vice versa.

Inventions II-IV are drawn to mutually exclusive and independent methods. Each of the methods of inventions II-IV require materially different and separate protocols, and none of the methods are required for the implementation of any other method.

Inventions II and any one of inventions V-IX are mutually exclusive and independent. The method of detection of invention II does not require the antibodies, kit or article of manufacture of inventions V-IX, and vice versa.

Inventions III and IV and any one of inventions V-IX are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies, kit and article of manufacture can be used to isolate E-cadherin.

Inventions V-IX are drawn to mutually exclusive and independent antibodies. Each of the antibodies of inventions V-IX are of separate design. Being of separate design is a criteria for independent inventions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (703) 308-1126. The examiner's SPE is Deborah Reynolds, whose telephone number is (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Art Unit Patent Analyst, Ms. Pauline Farrier, whose telephone number is (703) 305-3550.

The fax number is (703) 308-4242.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630

Dr. D. Crouch
May 21, 2002